

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: James A. Shayman

Continuation Application of

Application No.: 10/134,314

Filed: April 29, 2002

For: AMINO CERAMIDE-LIKE COMPOUNDS AND THERAPEUTIC  
METHODS OF USE

Date: 4-15-04

EXPRESS MAIL LABEL NO. EV214957287US

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☐ Copies of the cited references are enclosed.
    - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. 10/134,314, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
    - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. [    ], by [inventor(s)], filed [    ], Docket No.: [    ]  
\_\_\_\_\_ U.S. Patent Application No. [    ], by [inventor(s)], filed [    ], Docket No.: [    ]  
\_\_\_\_\_ U.S. Patent Application No. [    ], by [inventor(s)], filed [    ], Docket No.: [    ]

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Examiner

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Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [    ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.


Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[    ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By

  
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Concord, MA 01742-9133  
Dated: April 15, 2004

PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>April 15, 2004</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3646.1001-013		APPLICATION NO. Con't. of 10/134,314	
	FIRST NAMED INVENTOR James A. Shayman		FILING DATE	
	EXAMINER	CONFIRMATION NO.	GROUP	

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	5,916,911	06-29-1999	Shayman et al.
	AB	5,945,442	08-31-1999	Shayman et al.
	AC	5,952,370	09-14-1999	Shayman et al.
	AD	6,030,995	02-29-2000	Shayman et al.
	AE	6,040,332	03-21-2000	Shayman et al.
	AF	6,051,598	04-18-2000	Shayman et al.
	AG			
	AH			
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EXAMINER	DATE CONSIDERED
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR	Abe A., et al., "Improved Inhibitors of Glucosylceramide Synthesis," <i>J. Biochem.</i> , 111:191-196 (1992).	
AS	Alon, R., et al., "Glycolipid Ligands for Selections Support Leukocyte Tethering & Rolling Under Physiologic Flow Conditions," <i>J. Immunol.</i> , 154:5356-5366 (1995).	
AT	Bielawska, A., et al., "Modulation of Cell Growth and Differentiation by Ceramide," <i>FEBS Letters</i> , 307:211-214 (1992).	
AU	Blobe, G. C., et al., "Regulation of PKC and Its Role in Cancer Biology," <i>Cancer Metastasis Rev.</i> , 13:411-431 (1994).	
AV	Felding-Habermann, B., et al., "A Ceramide Analog Inhibits T Cell Proliferative Response Through Inhibition of Glycosphingolipid Synthesis and Enhancement of N,N-Dimethylsphingosine Synthesis," <i>Biochemistry</i> , 29:6314-6322 (1990).	
AW	Gatt, S., et al., "Assay of Enzymes of Lipid Metabolism with Colored and Fluorescent Derivatives of Natural Lipids," <i>Meth. Enzymol.</i> , 72:351-375 (1981).	
AX	Hakomori, S. "New Directions in Cancer Therapy Based on Aberrant Expression of Glycosphingolipids: Anti-adhesion and Ortho-Signaling Therapy," <i>Cancer Cells</i> , 3:461-470 (1991).	
AY	Hospattankar, A.V., et al., "Changes in Liver Lipids After Administration of 2-Decanoylamino-3-Morpholinopropiophenone and Chlorpromazine," <i>Lipids</i> , 17:538-543 (1982).	
AZ	Inokuchi, J., et al., "Antitumor Activity in Mice of an Inhibitor of Glycosphingolipid Biosynthesis," <i>Cancer Lett.</i> , 38:23-30 (1987).	
AR2	Inokuchi, J., et al., "Inhibition of Experimental Metastasis of Murine Lewis Long Carcinoma by an Inhibitor of Glucosylceramide Synthase and its Possible Mechanism of Action," <i>Cancer Res.</i> , 50:6731-6737 (1990).	
AS2	Inokuchi, J., et al., "Preparation of the Active Isomer of 1-Phenyl-2-Decanoylamino-3-Morpholino-1 Propanol, Inhibitor of Glucocerebroside Synthetase," <i>J. Lipid Res.</i> 28:565-571 (1987).	
AT2	Jaffrezou, J., et al., "Inhibition of Lysosomal acit Sphingomyelinase by Agents which Reverse Multidrug Resistance," <i>Biochem. Biophys. Acta</i> , 1266:1-8 (1995).	

EXAMINER	DATE CONSIDERED
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AU2	Radin, N.S., <i>et al.</i> , "Metabolic Effects of Inhibiting Glucosylceramide Synthesis with PDMP and Other Substances," In <i>Advances in Lipid Research; Sphingolipids in Signaling, Part B.</i> , R.M. Bell et al., Ed. (Academic Press, San Diego) 28:183-213 (1993).
	AV2	Radin, N.S., <i>et al.</i> , "Use of 1-Phenyl-2-Decanoylamino-3-Morpholino-1-Propanol (PDMP), an Inhibitor of Glucosylceramide Synthesis," In <i>Neuro-Protocols, A Companion to Methods in Neurosciences</i> , Fisher et al., Ed., (Academic Press, San Diego) 3:145-155 (1993).
	AW2	Rosenwald, A.G., <i>et al.</i> , "Effects of the Blycosphingolipid Synthesis Inhibitor, PDMP, On Lysosomes in Cultured Cells," <i>J. Lipid Res.</i> , 35:1232 (1994).
	AX2	Shayman, J.A., <i>et al.</i> , "Modulation of Renal Epithelial Cell Growth by Glucosylceramide: Association with Protein Kinase C, Sphingosine, and Diacylglyceride," <i>J. Biol. Chem.</i> , 266:22968-22974 (1991).
	AY2	Svensson, M., <i>et al.</i> , "Ephithelial Glucosphingolipid Expression as a Determinant of Bacterial Adherence and Cytokine Production," <i>Infect. And Immun.</i> 62:4404-4410 (1994).
	AZ2	Zador, I.Z., <i>et al.</i> , "A Role of Glycosphingolipid Accumulation in the Renal Hypertrophy of Streptozotocin-Induced Diabetes Mellitus," <i>J. Clin. Invest.</i> 91:797-803 (1993).
	AR3	Ziche, M., <i>et al.</i> , "Angiogenesis Can be Stimulated or Repressed in In Vivo by a Change in GM3:GD3 Ganglioside Ratio," <i>Lab. Invest.</i> , 67:711-715 (1992).

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